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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/072,782

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James D. Webb

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EXAMINER

MALLARI, PATRICIA C

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 04/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/072,782	Applicant(s) WEBB ET AL.	
	Examiner Patricia C. Mallari	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is a non-final rejection. New grounds of rejection have been introduced.

Claim Objections

Claims 10 and 26 are objected to because of the following informalities:

on line 13 of claim 10, the first word "and" should be replaced with "an";

on line 14 of claim 10, "device" should be replaced with "devices";

on the last line of claim 26 "stated" should be replaced with "state". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14 and 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the limitation "the plurality of implantable medical devices comprise a plurality of radio frequency receivers that receive the requests from the monitor", wherein multiple implantable medical devices receive the requests. However, Claim 10, upon which claim 14 depends, recites that the monitor transmits the request to "the at least one of the plurality of implantable medical device", wherein it is possible for only one implantable medical device to receive the requests. Therefore, it is unclear whether the requests are transmitted to at least one device or more than one medical device.

Claim 30 recites the limitation "a plurality of monitors . . . to receive and decrypt requests form the server . . . and transmit any unreceived request" on lines 11-18 of the claim. However, it is unclear how a monitor may transmit a request it has not received.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 7, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,720,770 to Nappholz et al. in view of US Patent No. 5,371,692 to Draeger et al. Nappholz discloses an external console 27 operating to receive and store at least one request to modify the behavior of an implantable medical device (IMD) 12, the at least one request received from and created by a clinician at a first selected time (col. 6, line 64- col. 7, line 64 of Nappholz). The remote console 27 operates as a server utilizing memory storage and a telemetry device to connect users in a network to a centralized store of information (figs. 1 and 6; col. 6, line 64 –col. 7, line 2; col. 7, lines 23-27; col. 7, lines 40-49; col. 8, lines 26-59 of Nappholz), and the description of the remote console 27 implies that some sort of input device or programmer must be included to allow the physician to enter instructions for entering the request (col. 7, lines 59-62 of Nappholz). A monitor 14 at a second location remote from the first location operates to receive the request from the server/remote console 27 (figs. 1, 6; col. 6, line 64-col. 7, line 7; col. 7, line 59-62 of Nappholz), subsequently conduct a programming

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telemetry session with the IMD 12, and transmit the at least one request to the IMD 12 at a second selected time (fig. 6; col. 7, line 5-8; col. 7, lines 60-64 of Nappholz), where figure 6 of Nappholz shows that the programming telemetry session and transmission of the at least one request to the IMD 12 occurs subsequent to the monitor 14 receiving the request from the server, since step 252 is shown as the step after step 250. A bi-directional communications system communicatively couples the server/remote console 27 and the monitor 14 (figs. 1 & 6; col. 7, lines 23-27; col. 7, lines 38-64 of Nappholz). Nappholz lacks verifying a status of the IMD indicating that the at least one request safely complies with a current programming state of the IMD.

However, Draeger et al. discloses a system wherein a monitor 13 sends a request to modify the behavior of a medical device 1, 1" (fig. 3; col. 7, lines 7-16; col. 7, line 67-col. 8, line 14 of Draeger). After initialization of communication with the medical device 1, 1" but prior to transmitting the request from the monitor 13 to the medical device 1, 1", the monitor 13 verifies a status of the medical device 1, 1" indicating that the request safely complies with a current programming state of the medical device 1, 1" (col. 8, lines 39-69 of Draeger). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the system of Draeger with that of Nappholz in order to prevent useless transmission of a program that has already been downloaded by the medical device (col. 8, lines 47-54 of Draeger).

Regarding claim 7, the second selected time may be substantially later than the first selected time (fig. 6; col. 7, lines 59-64 of Nappholz) wherein the second selected

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time is substantially later such that the first (step 248) and second time (step 252) are distinguishable as indicated.

Regarding claim 16, the request is transmitted to the IMD only if the request is determined to be safely compatible (fig. 6 of Draeger et al.)

Claims 4-6, 8, 9, 19, and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz in view of Draeger, as applied to claims 1, 7, and 16 above, and further in view of US Patent No. 6,249,705 to Snell. Nappholz, as modified, is silent as to encryption or decryption of the request. However, Snell teaches an apparatus in which information transmitted from a server 102 to a monitor 104 is subject to security measures including encryption (col. 7, lines 41-54 of Snell), wherein encryption implies that decryption would also have to occur in order to enable use of the data transmitted. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the apparatus of Snell with that of Nappholz, as modified by Draeger, in order to maintain data integrity in the server and monitor, to maintain appropriate safety levels for the patients being treated by the monitor, to maintain appropriate configuration controls for the monitors, and to maintain appropriate protection of patient data confidentiality (col. 7, lines 44-51 of Snell).

Regarding claims 5, 6, and 26, the monitor 14 transmits the request to the IMD 12 using a radio frequency transmitter 128 and the IMD 12 receives the request using a radio frequency receiver 25 (figs. 1-4A; col. 4, lines 6-11; col. 5, lines 15-18; col. 6, lines 10-16 of Nappholz).

Regarding claims 8 and 9, the monitor transmits the requests to a plurality of implantable medical devices 12 and the server allows the clinician to submit requests to at least one of the devices 12 (col. 6, line 64-col. 7, line 15; col. 7, lines 57-64; col. 8, lines 19-33 of Nappholz).

Regarding claims 19 and 22-25 the use of encryption between the server and the monitor forms a secure communication link between the first location (server and the second location (monitor). With further regard to claim 25, the monitor receives the request at a second time substantially later than the first time at which the programming initially occurs (fig. 6; col. 7, lines 59-64 of Nappholz), wherein the time difference between the step 248 of programming the request and the step 250 of transmitting the request to or receiving the request by the monitor 14 is substantial enough as to be distinguishable in time, as indicated by figure 6 of Nappholz.

Regarding claim 26, handshaking is employed between the server and the monitor, wherein handshaking involves notification that a device is ready to send and/or receive information (col. 8, lines 18-21 of Nappholz; col. 7, lines 51-54 of Snell). Also, the request is transmitted to medical device only if the current state of the medical device is determined to be safely compatible (fig. 6 of Draeger).

Claims 2, 3, 10, 13-15, 17, 18, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz in view of Draeger and Snell, as applied to claims 4-6, 8, 9, 19, and 22-26 above, and further in view of US Patent No. 6,132,363 to Freed et al. Nappholz, as modified, discloses using security measures and data integrity checks

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using any combination of hardware and software means, such as communications protocols to ensure the validity of data exchanged between the monitor and the server, but is silent as to the details of the communications protocols. However, Freed discloses a system employing data security and integrity requirements to guard against unauthorized access to controlling the operating parameters of an implantable medical device wherein the data security and integrity requirements include verifying that a person is authorized to submit a request (modify operating parameters) to the IMD (col. 11, line 50-col. 12, line 8; col. 12, line 51-col. 13, line 18 of Freed). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the data security and integrity requirements of Freed as the communications protocol of Nappholz, as modified by Draeger and Snell, since Nappholz, as modified, discloses using security measures and data integrity checks in the form of communications protocols, and Freed teaches user authorization as an appropriate such communications protocol employing security measures and data integrity checks.

Regarding claim 3, encryption provides a secure communication link between the server and the monitor (col. 7, lines 41-55 of Snell).

Regarding claims 13 and 14, the monitor 14 transmits the request to the IMD 12 using a radio frequency transmitter 128 and the IMD 12 receives the request using a radio frequency receiver 25 (figs. 1-4A; col. 4, lines 6-11; col. 5, lines 15-18; col. 6, lines 10-16 of Nappholz). With further regard to claim 14, the system may monitor and control a plurality of implantable medical devices 12 (col. 8, lines 19-33 of Nappholz).

Regarding claim 18, the system may employ a plurality of IMDs 12 (col. 8, lines 19-33 of Nappholz). A particular IMD 12 is selected by establishing communication between the monitor 14 and the server 27, where the monitor 14 transmits and receives information specific to a particular IMD 12 (fig. 6; col. 7, lines 32-64 of Nappholz).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz, in view of Draeger, Snell, and Freed, as applied to claims 2, 3, 10, 13-15, 17, and 27 above, and further in view of US Patent No. 6,047,325 to Jain et al. Nappholz, as modified, discloses encrypting communication to provide a secure connection, but is silent as to a particular means of doing so. However, Jain teaches that a virtual private network (VPN), created by encryption and authentication, provides a secure network (col. 2, lines 1-6 of Jain). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the VPN of Jain as the secure connection of Nappholz, as modified by Draeger, Snell, and Freed, since Nappholz, as modified, teaches using a secure connection, and Jain discloses a VPN as an appropriate means for doing so.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz, in view of Draeger, Snell, and Freed, as applied to claims 2, 3, 10, 13-15, 17, and 27 above, and further in view of US Patent 6,602,469 to Maus et al. Nappholz, as modified, discloses encrypting communication to provide a secure connection, but is silent as to a particular means for doing so. However Maus teaches that an Internet secure socket layer connection is well known in the art as a means of

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encryption/decryption (col. 20-25 of Maus). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the secure socket layer connection of Maus as the secure connection of Nappholz, as modified by Draeger, Snell, and ~~Reed~~, since Nappholz, as modified, discloses using a secure connection, and Maus describes a secure socket layer connection as such a secure connection.

Claims 20 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz, in view of Draeger and Snell, as applied to claims 4-6, 8, 9, 19, and 22-26 above, and further in view of US Patent No. 6,047,325 to Jain et al. Nappholz, as modified, discloses encrypting communication to provide a secure connection, but is silent as to a particular means of doing so. However, Jain teaches that a virtual private network (VPN), created by encryption and authentication, provides a secure network (col. 2, lines 1-6 of Jain). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the VPN of Jain as the secure connection of Nappholz, as modified by Draeger and Snell, since Nappholz, as modified, teaches ~~6581~~ using a secure connection, and Jain discloses a VPN as an appropriate means for

Claims 21 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz, in view of Draeger and Snell, as applied to claims 4-6, 8, 9, 19, and 22-26 above, and further in view of US Patent 6,602,469 to Maus et al modified, discloses encrypting communication to provide a secure connection, but is

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silent as to a particular means for doing so. However Maus teaches that an Internet secure socket layer connection is well known in the art as a means of encryption/decryption (col. 20, lines 20-25 of Maus). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the secure socket layer connection of Maus as the secure connection of Nappholz, as modified by Draeger and Snell, since Nappholz, as modified, discloses using a secure connection, and Maus describes a secure socket layer connection as such a secure connection.

Response to Arguments

Applicant's arguments with respect to claims 1-32 have been considered but are moot in view of the new grounds of rejection.

Allowable Subject Matter

Claims 31-32 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claim 30 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

The following is an examiner's statement of reasons for allowance:

Regarding claims 30-32, the prior art of record fails to teach or fairly suggest a system comprising a plurality of monitors, coupled to a bi-directional communication network to receive and decrypt requests to modify the behavior of at least one of a plurality of implantable medical devices from the server and to transmit any unreceived request to the at least one of the plurality of implantable medical devices in an order

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created on the programmer, and in combination with all of the other limitations of the claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia C. Mallari
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